This report is required by law (7 USC 2143.) Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Set attached form for additional information

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. **Certificate Number:** 34-R-0031

Customer Number: 696

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA include Zip Code)*

MPI Research Inc.
54943 N. Main Street
Mattawan, MI 49071

(269)668-3336

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS FORM 7023A).**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C +D + E)
4. Dogs	1,059	5,084	529	10	5,623
5. Cats	18	34	0	0	34
6. Guinea Pigs	38	64	163	0	227
7. Hamsters	15	51	0	0	51
8. Rabbits	259	1,899	327	3	2,229
9. Non-human Primates	1,104	2,818	304	0	3,122
10. Sheep	6	0	110	0	110
11. Pigs	285	778	1,392	0	2,170
12. Other Farm Animals					
13 Other Animals					
Chinchillas	6	0	74	0	74

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
(b)(6),(b)(7)(c)	(b)(6),(b)(7)(c)	19 NOV 07

API

(OCT 88), which is obsolete)

PART 1 – HEADQUARTERS

2072

MPI
RESEARCH

Column E Explanation

Registration Number: 34-R-0031

STUDY

- Number of Animals: 9 (50 on Study)
- Species: Dog

- Purpose of Study

  This was a Two-Week Oral Toxicity Study to evaluate the safety of the test article for submission to regulatory agencies.

- Explanation of Procedure Producing Pain and/or Distress

  The test and control articles were administered by oral capsules and tablets (placebo) daily to determine and evaluate the toxicity and toxicokinetics profile of the drug. All personnel were thoroughly trained. The animals were closely monitored by the technicians and the Study Director for general signs of toxicity. The general clinical observations were considered toxicity findings. These nine dogs died prior to administration of euthanasia solution.

- Scientific Justification

  The FDA (and International) regulations require this testing. The route of administration was considered the most appropriate by the Sponsor and the FDA to meet the objectives of this study. The dose levels administered were not expected to cause acute toxic effects. The immediate use of anesthetics, analgesics or tranquilizers would have masked the test article effects that needed to be characterized for appropriate safety evaluation.

- Regulations

  FDA Guidelines for Preclinical Toxicity Testing of Investigational Drugs for Human Use as well as generally accepted procedures for the testing of pharmaceutical compounds.

  Guidance for Industry, Investigators, and Reviewers: Exploratory IND Studies, U.S.F.D.A. Center for Drug Evaluation and Research (CDER), January 2006.

  Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals. ICH M3(M), 2000, November 9.

  International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines. Preclinical Safety Evaluation of Bio-Technology – Derived Pharmaceuticals ICH 56, July 1997. Note for Guidance on Toxicokinetics: The assessment of Systemic Exposure in Toxicity Studies S3A.

MPI
RESEARCH

Column E Explanation

Registration Number: 34-R-0031

STUDY

- Number of Animals: 3 (6 On Study)
- Species: Rabbit

- Purpose of Study

  This was an Acute Eye Irritation Study to evaluate the safety of the test article for submission to regulatory agencies.

- Explanation of Procedure Producing Pain and/or Distress

  The test article suspension was placed in the conjunctival sac of the right eye. Each of these animals had conjunctival redness for up to 48 hours and one animal also had swelling one hour postdose. No redness was noted in any animal after 48 hours and the swelling was not longer evident after 24 hours. All animals appeared normal 24 hours following dosing. The animals did not display any behaviors indicative of distress.

- Scientific Justification

  The FDA and OECD require this testing. The route of administration is directed in the guidelines to determine the toxicity and/or irritation resulting from ocular dosing of the test article for safety evaluation. The administration of any medications would alter the results of the study.

- Regulations

  FDA, 21 CFR Part 58.

  OECD, Guidelines for Testing of Chemicals, Guideline 405, April 2002.

MPI
RESEARCH

Column E Explanation

Registration Number: 34-R-0031

STUDY

- Number of Animals: 1 (24 On Study)
- Species: Dog

- Purpose of Study

  This was a 4-Week Oral Toxicity Study to evaluate the safety of the test article for submission to regulatory agencies.

- Explanation of Procedure Producing Pain and/or Distress

  The test article was administered by oral gavage. This animal had a dosing error resulting in progressive respiratory distress and unresponsiveness. This animal did not receive euthanasia in a timely manner to relieve the pain and distress. It died before the directed euthanasia procedure could be performed.

- Scientific Justification

  The route of administration was considered appropriate by the Sponsor and Study Director. All personnel were thoroughly trained and the animal was closely monitored by the technical staff and veterinarian. The clinical signs progressively worsened and administration of euthanasia solution could not be accomplished prior to the spontaneous death of the dog. This study was conducted to evaluate toxicity as required by the FDA.

- Regulations

  Guidance for Industry, Investigators, and Reviewers: Exploratory IND Studies, U.S.F.D.A. Center for Drug Evaluations and Research (CDER), January 2006.

  Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals. ICH M3(M), 2000, November 9.